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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/749,640

12/31/2003

Lawrence M. Boyd

1842-0021

9392

7590

02/12/2009

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EXAMINER

HARVEY, JULIANNA NANCY

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

02/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/749,640	Applicant(s) BOYD ET AL.	
	Examiner Julianna N. Harvey	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37,38 and 41-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37,38 and 41-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The declaration filed on 16 January 2009 under 37 CFR 1.131 is sufficient to overcome the Biedermann et al. (US 2005/0154390 A1) reference. This declaration, by Robert Rodrick, is sufficient taken in conjunction with the declaration by Lawrence Boyd, which was filed on 15 October 2008. First of all, the Rodrick declaration includes dates corresponding to actions taken from the alleged time of conception until the filing date of the present application (these dates were redacted from the Boyd declaration). Furthermore, the examiner specifically looked to the statements numbered 3 and 4 in the Rodrick declaration (pages 1-2) taken in conjunction with the exhibits and attachments referred to in those statements.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 35 has been renumbered 37.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 37, 41, 46, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley (US 6,610,091 B1) in view of Goble et al. (US 2002/0072800 A1). Regarding **claim 37**, Reiley discloses a method for dynamic stabilization of motion segments of the spine comprising the steps of: positioning a stabilization element ("500" in Fig. 12) adjacent the spine, the stabilization element configured to span a length of the spine between at least two vertebrae; engaging bone anchors ("330" in Fig. 12) to at least two vertebrae; and coupling the bone anchors to the stabilization element, with at least one of the bone anchors coupled to permit deflection ("315" may be made of rubber; col. 6, lines 7-24) of the bone anchor between the stabilization element and the corresponding vertebra to which the at least one of the bone anchors is engaged (Fig. 12; col. 8, lines 8-26; col. 9, lines 38-45; col. 10, lines 30-41). Regarding **claim 41**, Reiley discloses a method for dynamic stabilization of a motion segment of the spine comprising the steps of: coupling a dynamic stabilization system ("500" in Fig. 12) across the motion segment, the system including at least one bone anchor ("330" in Fig. 12) that permits natural motion of the disc by deforming a portion of the bone anchor ("315" may be made of rubber; col. 6, lines 7-24) (Fig. 12; col. 8, lines 8-26; col. 9, lines 38-45; col. 10, lines 30-41). Regarding **claim 46**, Reiley discloses that the bone anchor

Art Unit: 3733

includes an engagement portion (stem unlabeled in Fig. 12 but labeled as "310" in Fig. 4) configured for engagement within a vertebra of the motion segment, a head portion ("320" in Fig. 12) configured for engagement to a stabilization element outside the vertebral body, and a flexible portion ("315" in Fig. 12) between the engagement portion and the head portion. Regarding **claim 47**, Reiley discloses that the dynamic stabilization system includes a stabilization element ("500" in Fig. 12) configured to span a length of the spine between at least two vertebrae; and at least two anchors ("330" in Fig. 12), each of the anchors including a head portion ("320" in Fig. 12) configured for contacting the stabilization element and an engagement portion (stem unlabeled in Fig. 12 but labeled as "310" in Fig. 4) configured for engaging a vertebra, and at least one of the anchors including a flexible portion ("315" in Fig. 12) between the head portion and the engagement portion configured to permit relative movement between the head portion and the engagement portion. Reiley fails to teach repairing or replacing all or part of the intervertebral disc between at least two vertebrae (**claim 37**) and introducing a device into an intervertebral space to at least partially maintain or restore the natural motion of the disc at the motion segment (**claim 41**). Goble et al. teach that facet joint replacement in conjunction with artificial disc replacement recreates a fully functional motion segment that is compromised due to disease or trauma, and that together, facet joint and disc replacement can eliminate substantially all sources of pain, return full function and range of motion, and restore the natural biomechanics of the spinal column (para. 0011). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Reiley method

Art Unit: 3733

such that it includes repairing or replacing all or part of the intervertebral disc between at least two vertebrae (**claim 37**) and introducing a device into an intervertebral space to at least partially maintain or restore the natural motion of the disc at the motion segment (**claim 41**), as suggested by Goble et al., as doing so can eliminate substantially all sources of pain, return full function and range of motion, and restore the natural biomechanics of the spinal column.

Claims 38 and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley (US 6,610,091 B1) in view of Goble et al. (US 2002/0072800 A1) as applied to claims 37 and 41 above, and further in view of Bao et al. (US 5,534,028 A). Reiley and Goble et al. teach the claimed invention except that the step of repairing or replacing includes replacing all or part of the nucleus pulposus with a polymeric prosthesis having physical properties substantially similar to the physical properties of a natural nucleus pulposus (**claim 38**), that the device includes a device for replacing or augmenting the nucleus pulposus of the intervertebral disc (**claim 42**), that the step of introducing a device includes introducing a polymeric prosthesis to replace or augment the nucleus pulposus in which the polymeric prosthesis exhibits physical properties similar to the natural nucleus pulposus (**claim 43**), and that the polymeric prosthesis is formed from a hydrogel (**claim 44**). Bao et al. teach a prosthetic nucleus pulposus made of hydrogen, a polymer, that has physical properties that are substantially similar to the physical properties of a natural nucleus pulposus (col. 3, lines 13-24). It would have been obvious to one of ordinary skill in the art to further modify the Reiley method such that the disc replacement is the Bao et al. prosthetic nucleus pulposus (**claims 38**

Art Unit: 3733

and 42-44) as such a prosthesis is consistent with Goble et al. and would allow for partial disc replacement as some situations may only require replacement of the nucleus pulposus.

Claims 42 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley (US 6,610,091 B1) in view of Goble et al. (US 2002/0072800 A1) as applied to claim 41 above, and further in view of Fleischmann et al. (US 6,375,682 B1). Reiley and Goble et al. teach the claimed invention except that the device includes a device for replacing or augmenting the nucleus pulposus of the intervertebral disc (**claim 42**) and that the device for replacing or augmenting the nucleus pulposus is a mechanical device (**claim 45**). Fleischmann et al. teach a mechanical device for replacing the nucleus pulposus wherein the device can be adjusted to fit the individual patient and allows for post-operative adjustments (col. 6, lines 43-52; col. 3, lines 19-25). It would have been obvious to one of ordinary skill in the art to further modify the Reiley method such that the disc replacement is the Fleischmann et al. mechanical nucleus pulposus (**claims 38 and 42-44**) as such a prosthesis is consistent with Goble et al. and would allow for post-operative adjustments.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julianna N. Harvey whose telephone number is 571-270-3815. The examiner can normally be reached on Mon. - Fri., until 2:30 p.m.

Art Unit: 3733

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. N. H./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733